transportation and delivery mechanism in place to provide these emergent needs to the local and State authorities.

The Emergency Medical Device Shortage Survey was established in 1992 to collect data to assist FDA in implementing an emergency medical device shortage program that would find resources to supplement the needed supplies. In 2004, CDRH changed the process for the data collection and the name was changed to the Emergency Shortages Data Collection System. Because of the confidentiality aspect of the information, the information is only available to those on the FDA Emergency Shortage Team (EST) and senior management with a need-to-know. The need-to-know personnel include 5 EST members, the EST Leader, the EST data entry technician, and 5 senior managers.

The Emergency Shortages Data Collection System will be updated every 4 months to keep information current. CDRH learned that medical device manufacturers have a high rate of turnover in personnel and in corporate structures due to mergers with larger companies. In addition, with the constant advances in technology, some of these manufacturers are forced to discontinue product lines or add product lines to their inventory. This new data collection system process will update information on a regular basis ensuring more accurate information in an emergency/disaster.

The process consists of one scripted telephone call to the designated shortage person at the four or five largest manufacturers of specific medical devices that may be needed by first responders in a national emergency. At the current time, the list contains 67 products from 65 manufacturers. If other products or new technology are deemed necessary to add at a later date, then the EST will conduct the appropriate search to find the four or five largest manufacturers of that product line and request the manufacturer's voluntary inclusion into the program.

The Emergency Shortages Data Collection System will only include those medical devices that are expected to be in demand but in short supply in an emergency/disaster. The data collection system includes life-saving and life-sustaining products (i.e., mechanically powered ventilators) as well as products that would require frequent changes resulting in rapidly depleted supplies (i.e., face masks and gloves).

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
65	3	195	.5	98

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA based these estimates on past experience with direct contact with the medical device manufacturers. FDA estimates that approximately 65 manufacturers would be contacted by electronic mail three times per year to get updated information at their facility. Further, it is estimated that the manufacturers may require up to 30 minutes to check if information received previously is still current and send electronic mail back to FDA.

Dated: October 26, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–21973 Filed 11–3–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0516]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; 2005 Food Safety Survey; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration is correcting a notice that appeared in the Federal Register of October 24, 2005 (70 FR 61455). The document announced an approval by the Office of Management and Budget. The document was published with an incorrect expiration date for OMB control number 0910–0345. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In FR Doc. 05–21157, appearing on page 61455 in the **Federal Register** of Monday, October 24, 2005, the following correction is made:

1. On page 61455, in the second column, in the **SUPPLEMENTARY INFORMATION** section, beginning on line 13, the sentence "The approval expires on February 30, 2008." is corrected to read "The approval expires on February 29, 2008."

Dated: October 28, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–21974 Filed 11–3–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2002E–0020] (formerly Docket No. 02E–0020)

Determination of Regulatory Review Period for Purposes of Patent Extension; ZOMETA; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of February 28, 2003 (68 FR 9690). The document announced that FDA had determined the regulatory review period for ZOMETA. A Request for Revision of Regulatory Review Period was filed for the product on May 4, 2005. FDA reviewed its records and found that the effective date of the investigational new drug application (IND) was incorrect due to a clerical error. Therefore, FDA is revising the determination of the regulatory review period to reflect the correct effective date for the IND.

FOR FURTHER INFORMATION CONTACT: Claudia V. Grillo, Office of Regulatory Policy (HFD–13), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 240–453–6681.

SUPPLEMENTARY INFORMATION: In FR Doc. 03–4691, appearing on page 9690 in the **Federal Register** of February 28, 2003, the following corrections are made:

1. On page 9690, in the third column, in the first complete paragraph, in the third line, "2,810" is corrected to read "2,901"; in the fourth line, "2,201" is corrected to read "2,292".

2. On page 9690, in the third column, in the second complete paragraph, beginning in the fourth line, "December 12, 1993" is corrected to read "September 12, 1993"; in line 10, "December 12, 1993" is corrected to read "September 12, 1993".

Dated: October 20, 2005.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. 05–22012 Filed 11–3–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Pediatric Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Pediatric Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues. The committee also advises and makes recommendations to the Secretary under 45 CFR 46.407 on research involving children as subjects that is conducted or supported by the Department of Health and Human Services, when that research is also regulated by FDA.

Date and Time: The meeting will be held on Friday, November 18, 2005, from 8 a.m. to 2 p.m.

Location: Washington DC North/ Gaithersburg Hilton, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Jan N. Johannessen, Office of Science and Health Coordination of the Office of the Commissioner (HF–33), Food and Drug Administration, 5600 Fishers Lane (for express delivery, rm. 14C–06), Rockville, MD 20857, 301–827–6687, or by e-mail: *jjohannessen@fda.gov* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 8732310001. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss a report by the agency on Adverse Event Reporting, as mandated in Section 17 of the Best Pharmaceuticals for Children Act, for AGRYLIN (anagrelide), PARAPLATIN (carboplatin), DIFLUCAN (fluconazole), CAMPTOSAR (irinotecan), TAMIFLU (oseltamivir), VIOXX (rofecoxib), FERRLECIT (sodium ferric gluconate complex), and IMITREX (sumatriptan).

The background material will become available no later than the day before the meeting and will be posted under the Pediatric Advisory Committee Docket site at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm*. (Click on the year 2005 and scroll down to Pediatric Advisory Committee meetings.)

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by November 10, 2005. Oral presentations from the public will be scheduled on Friday, November 18, 2005, between approximately 8:30 a.m. and 9:30 a.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person by November 10, 2005, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Jan Johannessen at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: October 31, 2005.

Jason Brodsky,

Acting Associate Commissioner for External Relations.

[FR Doc. 05–22014 Filed 11–3–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committee on Special Studies Relating to the Possible Long-Term Health Effects of Phenoxy Herbicides and Contaminants (Ranch Hand Advisory Committee); Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Advisory Committee on Special Studies Relating to the Possible Long-Term Health Effects of Phenoxy Herbicides and Contaminants (Ranch Hand Advisory Committee).

General Function of the Committee: To advise the Secretary of Health and Human Services (the Secretary) and the Assistant Secretary for Health concerning its oversight of the conduct of the Ranch Hand study by the U.S. Air Force and provide scientific oversight of the Department of Veterans Affairs Army Chemical Corps Vietnam Veterans Health Study, and other studies in which the Secretary or the Assistant Secretary for Health believes involvement by the committee is desirable.

Date and Time: The meeting will be held on November 18, 2005, from 8:30 a.m. to 4 p.m.

Location: Food and Drug Administration, 5630 Fishers Lane, rm. 1066, Rockville, MD 20857.

Contact Person: Leonard Schechtman, National Center for Toxicological Research (HFT–10), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6696, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512560. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss the following items: (1) Updates and interactions with the Institute of Medicine's Air Force Health Study (AFHS) Disposition Study Committee; (2) AFHS closure preparations; (3) updates from the Air Force on the AFHS history, program management, and the Comprehensive Study Report; (4)